Complete Summary

GUIDELINE TITLE

Lipid screening in children and adolescents.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Lipid screening in children and adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 17 p. [16 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Familial hypercholesterolemia (FH)

IDENTIFYING INFORMATION AND AVAILABILITY

- Coronary heart disease (CHD)
- Coronary artery disease (CAD)

GUIDELINE CATEGORY

Evaluation Prevention Risk Assessment Screening

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To increase appropriate cholesterol screening for children at risk for familial hypercholesterolemia
- To increase the rate of history and exercise and nutrition assessments in the context of lipid screening of children
- To decrease inappropriate cholesterol screening for children

TARGET POPULATION

Children and young adults between the ages of 2 and up to 20 years whose family history includes a coronary heart disease event at a young age or profound hypercholesterolemia

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment of nutrition and exercise status
- 2. Evaluation of family history risk factors
- 3. Measurement of total serum cholesterol
- 4. Measurement of fasting total serum cholesterol, high density lipoprotein [HDL]-cholesterol, and triglycerides; calculation of low density lipoprotein [LDL]-cholesterol

MAJOR OUTCOMES CONSIDERED

- Prevalence of pediatric patients with familial hypercholesterolemia (FH)
- Sensitivity and specificity of cholesterol testing

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional descriptions of literature search strategies are available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline annotation, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member groups during an eight-week review period.

Each of the Institute's participating member groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are

developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating member groups following implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the responses received from member groups. Two members of the Preventive Services Steering Committee carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups? (3) Within the knowledge of the appointed reviewer, is the evidence cited in the document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three-six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline; the Preventive Services Steering Committee reviews the revised guideline and approves it for release.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations are presented in the form of an algorithm, <u>Lipid Screening in Children and Adolescents</u>, with 10 components and accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) grades are defined at the end of the "Major Recommendations" field.

Clinical Highlights

1. Increase appropriate cholesterol screening for children at risk for familial hypercholesterolemia. (Annotations #2, 5 and 7)

- 2. Screen by assessing nutrition and exercise status and by reviewing lipid status of first- degree relatives. (Annotation #3)
- 3. Obtain non-fasting total cholesterol level on patients between the ages of 2 and up to 20 years only if a first-degree relative has developed coronary heart disease before age 55 (male) or 65 (female) or has a cholesterol level greater than 300 mg/dL. (Annotation #6)
- 4. Obtain a fasting total cholesterol, high-density lipoprotein (HDL)-cholesterol, triglyceride, and calculated low-density lipoprotein (LDL)-cholesterol in patients whose total cholesterol is greater than or equal to 200 mg/dL. Repeat screening is not indicated until adulthood. (Annotation #8)
- 5. Individually case manage children or adolescents with a calculated LDL-cholesterol greater than or equal to 164 mg/dL. (Annotation #10)

<u>Introduction</u>

The only need for cholesterol screening in children and adolescents is to identify pediatric patients with familial hypercholesterolemia (FH), since early disease detection is crucial in order to facilitate treatment to prevent coronary artery disease. FH appears to be the only pediatric lipid disorder that requires treatment beyond the usual lifestyle counseling recommended for all children and adolescents.

This guideline focuses on patients whose family history includes a coronary heart disease (CHD) event at a young age or profound hypercholesterolemia. Its goal is to identify children and adolescents with FH through targeted cholesterol measurement in subpopulations whose members carry a higher likelihood of disease.

Evidence supporting this recommendation is of classes: C, R

Lipid Screening in Children and Adolescents Algorithm Annotations

1. Preventive Health Encounter

A preventive health encounter is a routinely scheduled well child visit in which the provider assesses the growth, development, and lifestyle of the individual. The Institute for Clinical Systems Improvement (ICSI) guidelines Preventive Counseling and Education and Preventive Counseling and Education and Preventive Services for Children and Adolescents would be implemented at this point.

2. Age Between 2 and Up to 20 Years and No Prior Screening?

The guideline applies to children and young adults between the ages of two and twenty years. Children prior to the age of two years do not require lipid status assessment. Adults 20 years old or older should be screened for their lipid status under the ICSI <u>Lipid Screening in Adults</u> guideline.

Once a child or adolescent has been screened any time between the ages of 2 to 20, they do not need to have the screening repeated.

3. Nutrition and Exercise Assessment/Family History Risk Factors

Please refer to the nutrition and physical activity section of the ICSI guideline Preventive Counseling and Education.

Children and young adults at risk for FH can be identified at any age by inquiring into the lipid status of their first-degree relatives. (First-degree relatives include parents and adult siblings.)

4. First-Degree Relative with a CHD Event at an Early Age?

A first-degree relative includes parents and adult siblings. CHD event at an early age includes occurrence prior to the age of 55 in men or prior to the age of 65 in women. If the family history is unobtainable, clinicians may wish to test the patient.

Evidence supporting this recommendation is of class: C

5. Parent with Pretreatment Total Cholesterol >300?

Adult FH heterozygotes have pretreatment cholesterol levels in the 300 to 500 mg/dL range. Adult FH homozygotes have untreated cholesterol levels greater than 500 mg/dl. Increase appropriate screening for children at risk for FH.

Evidence supporting this recommendation is of classes: D, R

6. Measure Total Cholesterol

Measurement of non-fasting serum total cholesterol is recommended for children and young adults who have either a first-degree relative with a history of premature CHD prior to the age of 55 years for men and 65 years for women, or a parent with a history of a total cholesterol greater than or equal to 300 mg/dL. The National Cholesterol Education Program (NCEP) guideline recommends chemical screening if parental levels are greater than or equal to 240 mg/dL.

7. Total Cholesterol > 200?

A total cholesterol of 200 mg/dL is the cutoff for individuals at risk for FH. Total cholesterol greater than or equal to 200 mg/dL requires further clinical assessment.

Evidence supporting this recommendation is of class: R

 Measure Fasting Total Cholesterol, HDL-Cholesterol, Triglycerides; Calculate LDL-Cholesterol

A fasting lipoprotein analysis will provide confirmation of any prior questionable or high screening results from non-fasting tests.

A fasting lipid panel should include a total cholesterol, HDL-cholesterol, triglycerides, and a calculated LDL-cholesterol. Fasting should occur over a period of nine to twelve hours prior to the blood draw for the lipid panel.

9. LDL-Cholesterol >164?

An LDL-cholesterol of 164 mg/dL has been shown to be the most discriminating level for identifying FH. Borderline levels (155-175 mg/dL) should be repeated to obtain an average. Clinicians should also obtain cholesterol levels from the parents. A markedly elevated level from one parent supports the diagnosis, while normal levels from both parents rules out FH.

Once a child has been tested and found to not have FH, no further testing is necessary until the individual is age 20, at which time they enter the ICSI <u>Lipid Screening in Adults</u> guideline. Clinicians should continue to review and offer praise or advice concerning diet and lifestyle at each routine health visit.

Evidence supporting this recommendation is of classes: D, R

10. Case Management/Out of Guideline

Children and young adults with an LDL-cholesterol greater than or equal to 164 mg/dL are considered to have FH and require individual management. These individuals are therefore no longer considered part of this guideline.

Additional follow-up with these individuals includes screening of the entire family and referral to a lipid specialty clinic for multidisciplinary management.

Definitions:

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A

Randomized, controlled trial

Class B

Cohort study

Class C

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R

- Narrative review
- Consensus statement
- Consensus report

Class X

Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for <u>Lipid Screening in Children and Adolescents</u>.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved identification of pediatric patients with familial hypercholesterolemia (FH) in order to facilitate treatment to prevent coronary heart disease

POTENTI AL HARMS

Not stated

QUALIFYING STATEMENTS

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- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the valuation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

RELATED NOMC MEASURES

- <u>Lipid screening in children and adolescents: percentage of children who are at risk for familial hypercholesterolemia who receive serum cholesterol screening.</u>
- <u>Lipid screening in children and adolescents: percentage of children with relevant family history of heart disease recorded and both exercise and nutrition assessments.</u>

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Lipid screening in children and adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 17 p. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 May (revised 2004 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUI DELI NE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health &: Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community

Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

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SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne, and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUI DELI NE COMMITTEE

Preventive Services Steering Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform users. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute For Clinical Systems Improvement (ICSI). Lipid screening in children and adolescents. Bloomington (MN): Institute For Clinical Systems Improvement (ICSI); 2003 Jun. 18 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Lipid screening in children and adolescents. In: ICSI pocket guidelines. April 2003 edition. Bloomington (MN): Institute For Clinical Systems Improvement (ICSI); 2003 Mar. p. 32-3.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 30, 1999. The information was verified by the guideline developer on October 11, 1999. This summary was updated by ECRI on May 15, 2000, December 30, 2003, and August 27, 2004.

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Date Modified: 11/8/2004



